K123925

SECTION 5: 510(k) SUMMARY

MAY 2 4 2013

510(k) SUMMARY
for
MTM® Clear Aligner In-Office

1. Submitter Information:

DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405

Contact Person: Helen Lewis
Telephone Number: 717-849-4229
Fax Number: 717-849-4343

Date Prepared: May 7, 2103

2. Device Name:

- Proprietary Name: MTM® Clear Aligner In-Office
- Classification Name: Aligner, Sequential
- CFR Number: 872.5470
- Device Class: II
- Product Code: NXC

3. Predicate Device:

Product Name	510(K)	Company Name
Invisalign® System	K081960	Align Technology, Inc.

4. Description of Device:

MTM® Clear Aligner In-Office is a system of plastic aligners fabricated in the dental professional's office that are modified with thermoplier accessories to create force points and spaces necessary for tooth movement by way of continuous gentle force. Commercially available auxiliaries such as hooks and orthodontic elastics may also be used in order to create the desired tooth movement. As the aligner is positioned on any particular tooth, the presence of the force points loads the polymeric shell material. The stored energy thus imparted into the elastomeric material of the aligner slowly dissipates over time as the bone underlying the tooth physiologically responds to the forces. After each desired incremental tooth movement has occurred, the aligner can be modified to increase the size of the force points or a new aligner may be fabricated. Each aligner moves the patient's teeth in small increments from their original state.

5. Indications for Use:

MTM® Clear Aligner In-Office is indicated for the treatment of anterior tooth malocclusions in patients with permanent dentition (i.e. all second molars). Utilizing a series of incremental minor tooth movements (torque, tipping, rotation and bodily movement), MTM® Clear Aligner sequentially positions teeth by way of continuous gentle force.

6. Description of Safety and Substantial Equivalence:

Technological Characteristics:

The MTM® Clear Aligners that are created in-office have the same technological characteristics as the predicate device, in that all the devices are made from commercially available plastic that is thermoformed to create a customized, patient-specific aligner. The aligners are then used for minor tooth movement by way of continuous gentle force.

In both systems, the aligners are created by thermoforming commercially available plastic material. The MTM® Clear Aligners are thermoformed by the healthcare practitioner in-office and in the case of the predicate device; the aligners are thermoformed by an outside laboratory. The plastic used for MTM Clear Aligners is cleared under K062828, Mouthguard and Aligner Material.

The MTM® Clear Aligner In-Office system incorporates the use of thermoplier accessories to create spaces and force points in order to cause minor tooth movement. These force points are located in specific areas and positioned in such a way that they provide a continuous force which slowly dissipates over time on the tooth to be moved for as long as the aligner is worn. The predicate device system also has the option of creating force points using pliers ("plier detailing") as a supplemental treatment to facilitate minor tooth movement..

With the MTM® Clear Aligner In-Office system, auxiliaries such as hooks, buttons, and orthodontic elastics may be used by the healthcare practitioner together with the aligner for the purpose of tooth movement. The H.I.T.® – Hook Inserting Tack System, is designed to insert external hooks onto the MTM® Clear Aligners for the purposes of attaching elastics. The H.I.T.® system consists of a H.I.T.® punch plier (used to punch a hole into the aligner into which the hook is inserted), a H.I.T.® insertion plier (used to insert the hook into the MTM® Clear Aligners), and the H.I.T.® hooks (a hook used to attach the elastics). Commercially available orthodontic elastics can be used to attach to the hooks. These auxiliaries are attached to the aligner and not the teeth, and the usage of these auxiliaries is determined by the dental practitioner. With the predicate system, the healthcare practitioner also has the option of using these types of auxiliary components in-office with the aligner for the purpose of tooth movement.

In both systems, the aligners can be removed by the patient at any time, and treatment can be discontinued at any time.

Non-Clinical Performance Data:

The MTM® Clear Aligner In-Office System is composed of existing, commercially available DENTSPLY Mouthguard and Aligner Materials which are cleared in premarket notification K062828. Material properties data derived from the methods described in ISO 20795-2 (*Dentistry – Base polymers – Part 2: Orthodontic base polymers*), ASTM D790 (*Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials*), ASTM D570 (*Standard Test Method for Water Absorption of Plastics*), and ASTM D256 (*Standard Test Method for Determining the Izod Pendulum Impact Resistance of Plastics*) for the aligner materials have been included to support substantial equivalence. No additional *in vitro* testing of finished, customized aligners has been included to support substantial equivalence. Clinical data is included to validate that the MTM® Clear Aligner meets the requirements of its intended use.

Clinical Performance Data

A clinical study was performed in order to support the safety and efficacy of the MTM® Clear Aligner In-Office System. The objective of the study was to demonstrate the ability of the MTM® Clear Aligner In-Office to achieve incremental minor tooth movement (including torque, tipping, rotation and bodily movement), using a series of aligners consistent with and fully supportive of the product's indications for use.

The three phase prospective open-label safety and effectiveness study included a pre-treatment period for establishing baseline root integrity and tooth position and to develop a treatment plan, an in-treatment monitoring period to document progression of the case, and a post-treatment period designed to establish final tooth position and root integrity. This data was also used to determine the magnitude of total tooth movement.

The study results included the following number of teeth successfully treated by sequential aligners:

- Torque 5 cases
- Tipping 7 cases
- Rotation 14 cases
- Bodily Movement 11 cases

No adverse events, including root resportion, were reported during the study.

Conclusion Regarding Substantial Equivalence:

MTM® Clear Aligner In-Office moves teeth by way of continuous gentle force through a sequence of clear aligners that follow the treatment plan developed by the clinician as does the predicate, Align System.

MTM® Clear Aligner In-Office is substantially equivalent to the predicate Invisalign System originally cleared under premarket notification K981095 and subsequently modified under premarket notification K081960. The MTM® Clear Aligner In-Office incorporates the same fundamental technology, is composed of similar materials, has the same intended use, and similar indications for use. Clinical data has been further provided to support the safety and efficacy of the MTM® Clear Aligner system when used within its proposed intended use. The conclusion of the design and intended use comparison of the MTM® Clear Aligner In-Office to the predicate device and the results of the clinical data included in this premarket notification support substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 24, 2013

Ms. Helen Lewis
Director Corporate Regulatory Affairs
DENTSPLY International, Incorporated
Susquehanna Commerce Center
221 West Philadelphia Street
YORK PA 17405

Re: K123925
Trade/Device Name: MTM® Clear Aligner In-Office
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NXC
Dated: April 30, 2013
Received: May 2, 2013

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

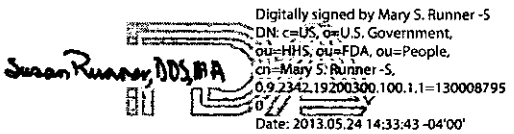
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K123925

Device Name: MTM® Clear Aligner In-Office

Indications for Use:

MTM® Clear Aligner In-Office is indicated for the treatment of anterior tooth malocclusions in patients with permanent dentition (i.e. all second molars). Utilizing a series of incremental minor tooth movements (torque, tipping, rotation and bodily movement), MTM® Clear Aligner sequentially positions teeth by way of continuous gentle force.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner, DDS, MPH

Digitally signed by Mary S. Runner -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner -S, 0.9.2342.19200300.100.1.1=1300087950
Date: 2013.05.10 08:33:22 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123925